PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#13
1 of 3
JRP
10/17/02

Applicant:	Joseph P. Steiner, et al.
Title:	Heterocyclic Ester and Amide Hair Growth Compositions and Uses
Appl. No.:	09/879,888
Filing Date:	June 14, 2001
Examiner:	Rebecca Cook
Art Unit:	1614

Commissioner for Patents
Washington, DC 20231

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

This brief answers the final Office Action of March 8, 2002. It is filed with two additional copies of the originally signed brief. It is accompanied by the small entity fee $160.00 under 37 C.F.R. § 1.17(c). It is timely, since it is filed within three months of the Notice of Appeal dated July 8, 2002, and accompanied by a Petition for an Extension of Time and the fee of $55.00 under 37 C.F.R. § 1.17(a)(1).

I. Real Party Interest

GPI NIL Holdings, Inc. is the real party in interest.

II. Related Appeals and Interferences

The following case is related to the present case: (1) Application No. 09/784,174, filed February 16, 2001.

III. Status Of Claims

Claims 17-33 are pending. Claims 1-16 are cancelled. Claims 17-33 are appealed.

IV. Status Of Amendments

All amendments were entered.

V. Summary Of Invention

The present invention relates to a pharmaceutical composition for treating alopecia or promoting hair growth using a heterocyclic ester or amide. Specification, p. 1, lines 12-15.

VI. Issues

There are four issues presented for review:

A. whether claim 33 is patentable under 35 U.S.C. § 102(b) over U.S. Patent 5,801,187;

B. whether claim 33 is patentable under 35 U.S.C. § 102(b) over U.S. Patent 6,200,972;

C. whether claim 33 is patentable under 35 U.S.C. § 102(b) over U.S. Patent 6,218,544; and

D. whether claims 17-32 are patentable under the judicially created doctrine of obviousness-type double patenting over claims 5-6 and 8 of copending U.S. Application No. 09/784,174.

VII. Grouping Of Claims

For the purpose of this appeal only, the claims stand or fall together for each ground of rejection which Appellant contests and which applies to a group of two or more claims.

VIII. Argument

A. The 35 U.S.C. § 102(b) rejection of claim 33 over U.S. Patent 5,801,187 is improper and should be reversed, because the evidence and explanation of record are insufficient to support the rejection.

An examiner has the initial burden of supporting an anticipation rejection. Yet the explanation of record never stated why the cited passages of the '187 patent describe the claimed invention. Specifically, according to the Examiner, "column 6, Formula I, claims" anticipates the claimed invention. Office Action, p. 2, ll. 8-9. But Formula I of column 6 describes a compound, and the claims do not recite a compound of Formula I. In any case, how can a disclosure of a compound, like that of the '187 patent's Formula I, anticipate a composition, like that of present claim 33? The record never provided an answer. Based on the explanation of record, it is respectfully submitted that the rejection is improper and should be reversed.

B. The 35 U.S.C. § 102(b) rejection of claim 33 over U.S. Patent 6,200,972 is improper and should be reversed, because the evidence and explanation of record are insufficient to support the rejection.

Preliminarily, according to its face, the '972 patent is believed to be a divisional of the '187 patent, the patent discussed in Section A of this brief.

The explanation of record never stated why the cited passages of the '972 patent describe the claimed invention. Specifically, according to the Examiner, "column 3, Formula I, claims" anticipates the claimed invention. Office Action, p. 2, ll. 8-9. But Formula I of either column 3 or the claims describes a compound. Again, a disclosure of compound, like that of the '972 patent's Formula I, cannot anticipate a composition, like that of present claim 33. As the explanation of record never stated where the '972 application describes the claimed invention, the rejection is improper and should be reversed.

C. The 35 U.S.C. § 102(b) rej ction of claim 33 over U.S. Patent 6,218,544 is improper and should be reversed, because th evidenc and xplanation of r cord are insuffici nt to support the r j ction.

Preliminarily, according to its face, the '544 patent is believed to be a divisional of U.S. Application No. 09/027,622, which produced the '972 patent, the patent discussed in Section B of this brief. The '972 patent is believed to be a divisional of the '187 patent, the patent discussed in Section A of this brief.

The explanation of record never stated why the cited passages of the '544 patent describe the claimed invention. Specifically, according to the Examiner, "column 3, Formula I" anticipates the claimed invention. Office Action, p. 2, ll. 8-9. But Formula I of column 3 describes a compound, not a composition, like that of present claim 33. As the explanation of record never stated where the '544 application describes the claimed invention, the rejection is improper and should be reversed.

D. The nonstatutory double patenting rejection of claims 17-32 ov r claims 5-6 and 8 of copending U.S. Application No. 09/784,174 is improp r and should be reversed, because the evidence and explanation of record are insufficient to support the rejection.

The Examiner urged that claims 17-32 of the present application are a prima facie obvious variation of claims 5-6 and 8 of the '174 application. Office Action of 3/8/2, p. 3, ll. 4-8. But the evidence and explanation of record are insufficient to support the rejection.

A factual finding that is material to patentability can neither stand if it is supported only by conclusory statements nor be resolved on the subjective belief of an examiner. In re Lee, 277 F.3d 1338, 1346, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). A material finding is the motivation to combine/modify in the section 103 context. Id. Since determinations of prima facie obviousness in the section 103

context parallel those in the double patenting context, MPEP § 804 II. B. 1, any core factual determination in the double patenting context is material to patentability. Thus, a core factual determination in the double patenting context can neither stand if it is supported only by conclusory statements nor be resolved on the subjective belief of an examiner.

More particularly, each double patenting rejection should make clear both (1) the differences between the allegedly conflicting claims and (2) the reason why one of ordinary skill in the art would conclude the presently claimed invention is a prima facie obvious variation of allegedly conflicting claims. MPEP § 804 II. B. 1. But in this rejection the Examiner never made clear sufficient findings for either (1) or (2). Finding (1) was not made of record. Finding (2) consists of noting that there might be overlap between the two sets of claims. Office Action, p. 3, ll. 11-13. Of course, overlap differs from double patenting. MPEP § 804 II. One set of claims overlaps another set if the first set is broad enough to embrace at least part of the second set. Overlap itself, however, cannot establish a prima facie case of nonstatutory double patenting. Id.

As a whole, the record indicates that the Examiner either merely concluded the present claims are a prima facie obvious variation of the cited claims of the '174 application or merely resolved the issue based on the Examiner's subjective belief. Either way, the rejection is improper and should be reversed.

IX. Appendix

An appendix containing a copy of the claims involved in the appeal is attached.

X. Conclusion

Each rejection should be reversed and the application allowed.

Respectfully submitted,

Dated: October 8, 2002

By: _____
Sean A. Passino
Reg. No. 45,943

If any [further] extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 19-0741.

APPENDIX

17. A pharmaceutical composition which comprises:

(i) an effective amount of a nitrogen-containing heterocyclic compound having two or more heteroatoms,

wherein said compound has a substituent –C(W)–C(Y)– which is attached to a nitrogen atom of the heterocyclic ring,

wherein W and Y are independently selected

from the group consisting of O, S, CH_2, and H_2, and

wherein said compound is additionally substituted with a ester or amide substituent attached to any atom of the heterocyclic ring other than said nitrogen atom,

provided that said ester or amide substituent is not an N-oxide of an ester or amide and further provided that said amide substituent is linked to the heterocyclic ring with a carbon-carbon bond;

(ii) a second compound for treating alopecia or promoting hair growth; and

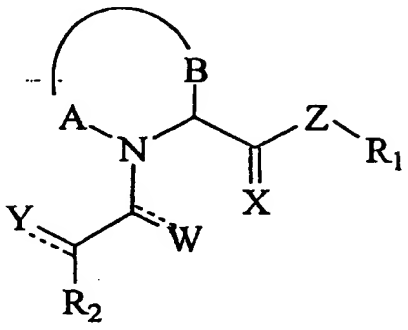
(iii) a pharmaceutically acceptable carrier.

18. The pharmaceutical composition of claim 17, wherein the compound is non-immunosuppressive.

19. The pharmaceutical composition of claim 17, wherein the compound has an affinity for an FKBP-type immunophilin.

20. The pharmaceutical composition of claim 19, wherein the FKBP-type immunophilin is FKBP-12.

21. The pharmaceutical composition of claim 17, wherein the compound is of formula I



I

or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

A and B, together with the nitrogen and carbon atoms to which they are respectively attached, form a 5-7 membered saturated or unsaturated heterocyclic ring containing, in addition to the nitrogen atom, one or more additional O, S, SO, SO_2, N, NH, or NR_1 heteroatom;

X is O or S;

Z is O, NH, or NR_1;

W and Y are independently O, S, CH_2, or H_2;

R_1 is C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, which is substituted with one or more substituent(s) independently selected from the group consisting of $(Ar_1)_n$, C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl substituted with $(Ar_1)_n$, C_3-C_8 cycloalkyl, C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl substituted with C_3-C_8 cycloalkyl, and Ar_2;

n is 1 or 2;

R_2 is either C_1-C_9 straight or branched chain alkyl, C_2-C_9 straight or branched chain alkenyl, C_3-C_8 cycloalkyl, C_5-C_7 cycloalkenyl or Ar_1,

wherein said alkyl, alkenyl, cycloalkyl or cycloalkenyl is either unsubstituted or substituted with one or more substituent(s) independently selected from the group consisting of C_1-C_4 straight or branched chain alkyl, C_2-C_4 straight or branched chain alkenyl, and hydroxy; and

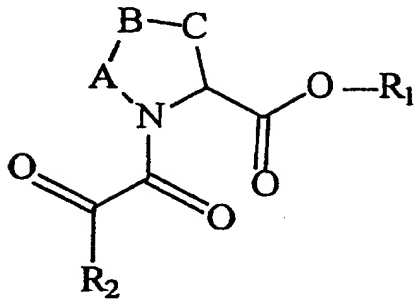
Ar_1 and Ar_2 are independently an alicyclic or aromatic, mono-, bi- or tricyclic, carbo- or heterocyclic ring,

wherein the ring is either unsubstituted or substituted with one or more substituent(s) independently selected from the group consisting of halo, hydroxy, nitro, trifluoromethyl, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_1-C_4 alkoxy, C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino, wherein the individual ring size is 5-6 members, and wherein the heterocyclic ring has 1-6 heteroatom(s) independently selected from the group consisting of O, N, and S.

22. The pharmaceutical composition of claim 21, wherein said Ar_1 or Ar_2 is selected from the group consisting of naphthyl, indolyl, furyl, thiazolyl, thienyl, pyridyl, quinolinyl, isoquinolinyl, fluorenyl, and phenyl.

23. The pharmaceutical composition of claim 21, wherein the one or more additional heteroatom(s) in the 5-7 membered saturated or unsaturated heterocyclic ring is NH or NR_1.

24. The pharmaceutical composition of claim 17, wherein the compound is of formula II



II

or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

A, B and C are independently CH_2, O, S, SO, SO_2, NH, or NR_1, provided that A, B and C are not all CH_2;

R_1 is C_1-C_5 straight or branched chain alkyl or C_2-C_5 straight or branched chain alkenyl, which is substituted with one or more substituent(s) independently selected from the group consisting of $(Ar_1)_n$ and C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl substituted with $(Ar_1)_n$;

n is 1 or 2;

R_2 is either C_1-C_8 straight or branched chain alkyl, C_2-C_9 straight or branched chain alkenyl, C_3-C_8 cycloalkyl, C_5-C_7 cycloalkenyl, or Ar_1; and

Ar_1 is a an alicyclic or aromatic, mono-, bi- or tricyclic, carbo- or heterocyclic ring,

wherein the ring is either unsubstituted or substituted with one or more substituent(s) independently selected from the group consisting of halo, hydroxy, nitro, trifluoromethyl, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_1-C_4 alkoxy, C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino wherein the individual ring size is 5-6 members and wherein the heterocyclic ring has 1-6 heteroatom(s) independently selected from the group consisting of O, N, and S.

25. The pharmaceutical composition of claim 24, wherein:

A is CH_2;

B is CH_2 or S;

C is CH_2 or NH;

R_1 is selected from the group consisting of 3-phenylpropyl and 3- (3-pyridyl) propyl; and

R_2 is selected from the group consisting of 1, 1-dimethylpropyl, cyclohexyl, and *tert*-butyl.

26. The pharmaceutical composition of claim 25, wherein:

B is CH_2;

C is NH; and

R_1 is 3-phenylpropyl.

27. The pharmaceutical composition of claim 25, wherein:

B is S; and

C is CH_2.

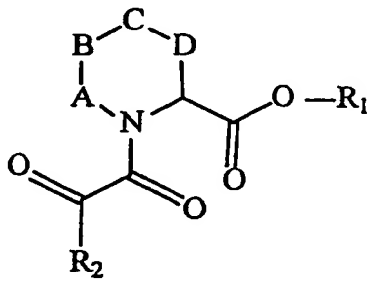
28. The pharmaceutical composition of claim 24, wherein the compound is selected from the group consisting of:

3-phenyl-1-propyl (2*S*) -1- (3,3-dimethyl-1,2-dioxopentyl)-2-(4-thiazolidine) carboxylate; and

3-(3-pyridyl)-1-propyl (2*S*)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-(4-thiazolidine) carboxylate;

or a pharmaceutically acceptable salt, ester, or solvate thereof.

29. The pharmaceutical composition of claim 17, wherein the compound is of formula III



III

or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

A, B, C and D are independently CH_2, O, S, SO, SO_2, NH, or NR_1, provided that A, B, C and D are not all CH_2;

R_1 is C_1-C_5 straight or branched chain alkyl or C_2-C_5 straight or branched chain alkenyl, which is substituted with one or more substituent(s) independently selected from the group consisting of $(Ar_1)_n$ and C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl substituted with $(Ar_1)_n$;

n is 1 or 2;

R_2 is either C_1-C_9 straight or branched chain alkyl, C_2-C_9 straight or branched chain alkenyl, C_3-C_8 cycloalkyl, C_5-C_7 cycloalkenyl, or Ar_1; and

Ar_1 is an alicyclic or aromatic, mono-, bi- or tricyclic, carbo- or heterocyclic ring,

wherein the ring is either unsubstituted or substituted with one or more substituent(s) independently selected from the group consisting of halo, hydroxy, nitro, trifluoromethyl, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_1-C_4 alkoxy, C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino wherein the individual ring size is 5-6 members and wherein the heterocyclic ring has 1-6 heteroatom(s) independently selected from the group consisting of O, N, and S.

30. The pharmaceutical composition of claim 29, wherein:

A is CH_2;

B is CH_2;

C is S, O or NH;

D is CH_2;

R_1 is selected from the group consisting of 3-phenylpropyl and (3, 4, 5-trimethoxy) phenylpropyl; and

R_2 is selected from the group consisting of 1,1-dimethylpropyl, cyclohexyl, *tert*-butyl, phenyl, and 3, 4, 5-trimethoxyphenyl.

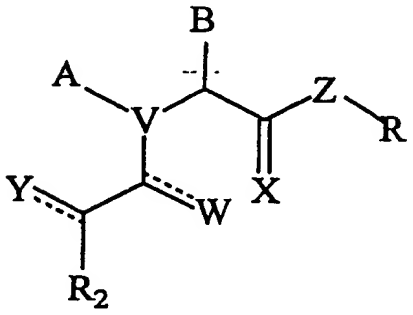
31. The compound of claim 30, wherein:

C is NH; and

R_2 is 1,1-dimethylpropyl or phenyl.

32. A pharmaceutical composition which comprises:

(i) a compound of formula IV



IV

or a pharmaceutically acceptable salt, ester, or solvate thereof, wherein:

V is CH or N;

A and B, taken together with V and the carbon atom to which they are respectively attached, form a 5-7 membered saturated or unsaturated heterocyclic ring containing, in addition to V, one or more heteroatom(s) independently selected from the group consisting of O, S, SO, SO_2, N, NH, and NR;

R is either C_1-C_9 straight or branched chain alkyl, C_2-C_9 straight or branched chain alkenyl, C_3-C_9 cycloakyl, C_5-C_7 cycloalkenyl, or Ar_3,

wherein R is either unsubstituted or substituted with one or more substituent(s) independently selected from the group consisting of halo, haloalkyl, carbonyl, carboxy, hydroxy, nitro, trifluoromethyl, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_1-C_4 alkoxy, C_2-C_4 alkenyloxy, phenoxy, benzyloxy, thioalkyl, alkylthio, sulfhydryl, amino, alkylamino, aminoalkyl, aminocarboxyl, and Ar_4

Ar_3 and Ar_4 are independently an alicyclic or aromatic, mono-, bi- or tricyclic, carbo- or heterocyclic ring;

wherein the individual ring size is 5-8 members wherein said heterocyclic ring has 1-6 heteroatom(s) independently selected from the group consisting of O, N, and S;

X is O or S;

Z is O, NH, or NR_1, W and Y are independently O, S, CH_2, or H_2;

R_1 is C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, which is substituted with one or more substituent(s) independently selected from the group consisting of $(Ar_1)_n$, C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl substituted with $(Ar_1)_n$ C_3-C_8 cycloalkyl, C_1-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl substituted with C_3-C_8 cycloalkyl, and Ar_2;

n is 1 or 2; and

R_2 is either C_1-C_9 straight or branched chain alkyl, C_2-C_9 straight or branched chain alkenyl, C_3-C_8 cycloalkyl, C_5-C_7 cycloalkenyl or Ar_1,

wherein said alkyl, alkenyl, cycloalkyl or cycloalkenyl is either unsubstituted or substituted with one or more substituent(s) independently selected from the group consisting of C_1-C_4 straight or branched chain alkyl, C_2-C_4 straight or branched chain alkenyl, and hydroxy;

(ii) a second compound for treating alopecia or promoting hair growth; and

(iii) a pharmaceutically acceptable carrier.

33. A pharmaceutical composition which comprises:

(i) an effective amount of a nitrogen-containing heterocyclic compound having two or more heteroatoms,

wherein said compound has a substituent -C(W) -C(Y)- which is attached to a nitrogen atom of the heterocyclic ring, wherein W and Y are independently selected from the group consisting of O, S, CH_2, and H_2, and

wherein said compound is additionally substituted with an ester or amide substituent attached to any atom of the heterocyclic ring other than said nitrogen atom,

provided that said ester or amide substituent is not an N-oxide of an ester or amide and further provided that said amide substituent is linked to the heterocyclic ring with a carbon-carbon bond; and

(ii) a pharmaceutically acceptable carrier.

PATENT

Attorney Docket No.: 054707/0171

1614

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Joseph P. Steiner, et al.

Title: Heterocyclic Ester and Amide Hair Growth Compositions and Uses

Appl. No.: 09/879,888

Filing Date: June 14, 2001

Examiner: Rebecca Cook

Art Unit: 1614

Commissioner for Patents
Washington, DC 20231

Sir:

I. TRANSMITTAL OF APPEAL BRIEF (37 C.F.R. 1.192)

Enclosed are three copies of an APPEAL BRIEF which follow the Notice of Appeal of July 8, 2002.

This application is on behalf of a

☒ Small Entity ☐ Large Entity

Pursuant to 37 C.F.R. 1.17(f), the fee for filing the Appeal Brief is:

☒ $160.00 (Small Entity)

☐ $320.00 (Large Entity)

TOTAL FEE DUE:

Notice of Appeal Fee	$160.00
Extension Fee (if any)	$55.00
Total Fee Due	$215.00

☒ Enclosed is a check for $215.00 to cover the above fees.

Respectfully submitted,

Dated: October 8, 2002

By: _____
Sean A. Passino
Reg. No. 45,943

Robin McKinney ?
202-408-4000

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this Appeal Brief and such extension has not otherwise been requested such an extension is hereby requested and the Commissioner is authorized to charge necessary fees for such an extension to our Deposit Account No. 19-0741. A duplicate copy of this paper is enclosed for use in charging the deposit account.